

## **REMARKS**

### **I. Amendments**

Applicants are appreciative of the favorable indication that claims 3-14 and 18-24 are directed to patentable subject matter. Applicants submit that the remaining claims 1, 2, 15-17, 27-29, and 38 are also directed to patentable subject matter in view of the amendments and arguments presented herein.

### **II. Rejection under 35 U.S.C. §112, first paragraph**

Claims 32, 35, and 36 remain rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement for the reasons of record.

In order to expedite prosecution, Applicants have cancelled claims 32, 35, and 36. Accordingly, the rejection under §112, first paragraph, is moot and should be withdrawn.

Applicants reserve the right to file a continuation application to resume prosecution of the subject matter of any of the cancelled claims.

### **III. Rejection under 35 U.S.C. §103(a)**

Claims 1, 2, 15-17, 27-29, and 38 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over each of the following four documents:

WO 2003/094967 to Hanauer et al. (“Hanauer”);  
WO 2002/064118 to Juppo et al. (“Juppo”);  
WO 2002/020523 to Elman et al. (“Elman”); and  
WO 1999/055706 to Amin et al. (“Amin”).

The Examiner alleges that each of the four documents discloses the instant compound, i.e., 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo-[1,2-a]pyridine-6-carboxamide (“the compound”), pharmaceutical composition, and method of using the compound. The Examiner acknowledges, however, that each of the cited documents does not disclose the specific claimed mesylate salt, but alleges that one of ordinary skill in the art would have been motivated to modify the disclosed compound to obtain the instant claimed mesylate salt. The Examiner also alleges that changing one salt to another is within the skill of the artisan and that mesylate is a common salt.

For the reasons of record, Applicants maintain that the claimed mesylate compounds are not disclosed or suggested by the prior art. Furthermore, there is no suggestion in the prior art that the compound in the form of a mesylate salt would advantageously impart an unexpected and superior improvement in therapeutic effect.

In the Office Action mailed March 31, 2008, the Examiner has acknowledged that the comparative data submitted by Applicants in the Amendment, dated January 10, 2008, shows unexpected properties for the claimed mesylate salt. The Examiner has suggested that Applicants submit the comparison data found on page 15 of the previously-filed Amendment in the form of a Declaration, and has verbally informed Applicants that submission of this data in the form of a Declaration would be persuasive in refuting the obviousness rejection.

Accordingly, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 (hereinafter the “Declaration”) in the name of Ursula Hohlneicher. The Declaration is comprised of the comparative data that was submitted on pages 14-17 of Applicants’ Amendment, dated January 10, 2008, in response to the Office Action, mailed July 13, 2007. The Declaration provides a comparison of the claimed mesylate salt with the corresponding free base and HCl salt.

Exhibit B of the Declaration demonstrates the unexpected and superior dissolution behavior of the claimed mesylate salt as compared to the free base and HCl salt. As is apparent from the comparative data, the claimed mesylate salt has a significantly higher dissolution rate in human intestinal fluids over the free base and HCl salt. For example, the comparative data demonstrates that the mesylate salt attains a concentration of 50 µg/ml in intestinal fluids after approximately 20 seconds, whereas the free base and HCl salt do not reach this concentration even after 900 seconds.

The above biological test data unequivocally demonstrates that the claimed mesylate salt has unexpectedly superior dissolution properties in human intestinal fluid as compared to the free base and HCl salt, and this improvement is not suggested by any of the cited art. It is precisely this type of “greater than expected result” which has long been an evidentiary factor pertinent to a finding of nonobviousness. (*United States v. Adams*, 383 U.S. 39, 51-52 (1966)). These properties would not have been predictable to one of ordinary skill in the art in view of Hanauer,

Juppo, Elman, or Amin. Therefore, the pending claims are nonobvious, and withdrawal of the rejection of claims 1, 2, 15-17, 27-29, and 38 under 35 U.S.C. §103(a) is respectfully requested.

#### **IV. Conclusion**

Upon entry of this Amendment, claims 1-24, 27-29, and 38 remain pending. Applicants respectfully submit that the pending claims are directed to patentable subject matter. Accordingly, Applicants request expedited allowance of the instant application. No new matter has been added by any amendment herein.

Authorization is hereby given to charge any fee in connection with this communication to Deposit Account No. 23-1703.

Dated: July 30, 2008

Respectfully submitted,

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